GUIDELINE FOR THE EVALUATION OF GENERAL PURPOSE DIAGNOSTIC X-RAY EQUIPMENT

State of Utah
Department of Environmental Quality
Division of Radiation Control

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DRC Inspection Program Objective

The overall objective of the Division of Radiation Control (DRC) x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that the equipment satisfies the appropriate regulatory standards for calibration and performance.

Purpose of Guideline

The intent and purpose of this document is to provide users of **general purpose diagnostic x-ray equipment** guidelines for the documentation necessary to demonstrate to the DRC that the x-ray equipment satisfies the regulatory standards under clinical use conditions.

X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met:

1) Adequate total filtration is present.
2) kVp calibration is adequate for the mA stations (mAs stations if mA is not a technique factor that can be chosen) used clinically.
3) mAs reciprocity is satisfied.
4) The timer, if present, is accurate for those time values most frequently used.
5) Exposures are reproducible.
6) The x-ray field is collimated and aligns with the image receptor as follows:
- **a)** The x-ray and light fields are congruent;
- **b)** Light field intensity is adequate;
- **c)** If the under table bucky and/or the wall mounted vertical cassette holder is used clinically, the center of the x-ray field can be aligned with the center of the film;
- **d)** If the equipment has a clinically used positive beam limiting device (PBL), exposures can not be made unless the x-ray field is collimated to an acceptable field size;
- **e)** When a PBL is not present and the under table bucky is used, the collimator field size indicator is accurate within the regulatory requirements; and
- **f)** Appropriate source to image receptor distance (SID) indicators are present to allow positioning of the x-ray source relative to the image receptor in a reproducible manner.

The following examples are presented as guidance for what will be considered an adequate evaluation, with support documentation, to demonstrate compliance:

1) Adequate Filtration

Demonstration of adequate filtration shall be accomplished by showing that the half value layer (HVL) exceeds the minimum regulatory standard. For example, at a measured kVp value of 80, the HVL is to be equal to or greater than 2.3 mm aluminum. This can be demonstrated by:

a) Measuring the in air exposure when different thicknesses of aluminum intercept the x-ray beam and calculating the HVL value; or

b) Measuring the exposure at 80 kVp with and without a 2.5 mm aluminum absorber intercepting the x-ray beam and showing that the ratio of the two exposure values exceeds 0.5.

(Documentation shall include a listing of the measured exposure values and associated thicknesses of aluminum.)

2) kVp Calibration

Accuracy of the kVp is to be determined under simulated clinical conditions.

Example 1: Over ninety percent of the x-ray exams performed on a particular x-ray unit are chest procedures and above table extremities. Chest procedures are performed at 80 to 95 kVp on either the 200 or 300 mA stations. Extremities are performed at 50 to 65 kVp on the 100S mA station. As a minimum, the kVp is to be measured on both the 200 and 300 mA stations for at least one kVp setting in the 80 to 95 kVp range and on the 100S station for a kVp setting in the 50 to 60 range.

Example 2: Chest, abdominal and extremity procedures are performed with a high frequency generator using programmed technique factors. For a given procedure and view, the kVp is automatically chosen. The patient thickness is entered by the operator and a mAs value is automatically chosen. Chests are performed at 120 kVp with mAs values typically in the 1.5 to 10 range. Extremity procedures are performed at 50 to 60 kVp with mAs values in the 1 to 10 range. Abdomens are performed at 75 to 85 kVp with mAs values in the 20 to 100 range. A minimum evaluation of kVp calibration will be a measurement of the kVp using an appropriate mAs for each of the above three procedures; i.e., 120 kVp at a mAs value in the range of 1 to 10, 80 kVp with a mAs value in the range 20 to 100, and 60 kVp at a mAs value in the range of 1 to 10.

(Documentation shall include the kVp values measured, the mA and mAs values used, and the results of such measurements.)

3) mAs Reciprocity

The regulatory standards require only a limited mAs reciprocity be satisfied as follows:

a) Output linear in mA: For a given kVp and fixed time value (mAs value if time is not a technique factor), the difference in the mR/mAs exposure on any two adjacent mA stations, or two mA stations differing by no more than a factor of two, shall not differ by more than 0.10 times the sum of the two values;

b) Output linear in time: For a given kVp selection and mA station, the difference in the mR/mAs exposure on any two consecutive time settings, or at two or more settings not differing by more than a factor of two, shall not differ by more than 0.10 times their sum.

c) Output linear in mAs: For a given kVp and mAs value (time is not a technique factor and there is no tube current selector but a continuous change in tube current with mAs value.) the difference in the mR/mAs output on any two adjacent mAs settings, or at two setting differing by no more than a factor of two, shall not differ by more than 0.10 times their sum.

Example 1: A facility uses a single phase full rectified x-ray generator for chest and extremity procedures. Chests are performed at 110 kVp using either the 200 or 300 mA stations and one of the following timer values; 1/60, 1/40, 1/30 or 1/20 seconds. Extremities are performed at 50 to 60 kVp on the 100 mA station at either 1/20 or 1/10 seconds. As a minimum, the linearity in the 200 and 300 mA stations at 110 kVp will be evaluated and the linearity in time is to be evaluated for at least one of the two procedures. For chests, the mR/mAs exposure will be measured at 110 kVp on one of the mA stations used clinically (either the 200 or 300 mA station) and for the exposure times in the range of 1/60 to 1/20 seconds. For extremities, the mR/mAs exposure will be measured at 50 or 60 kVp on the 100 mA station and for timer values in the range of 1/20 to 1/10 seconds.

Example 2: A facility is using a new high frequency generator where console programmed variable mAs techniques are being used. The specific kVp and mAs values are automatically chosen depending on the procedure, desired view, and the patient thickness which is entered by the radiographer. Chest procedures are performed at 120 kVp with mAs values typically in the 1.5 to 10 range. Extremity procedures are performed at 50 to 60 kVp with mAs values in the 1.0 to 10 range. Abdomens are performed at 75 to 85 kVp with mAs values in the 20 to 100 range. As a minimum, linearity is to be evaluated for at least one of the three procedures. For chest procedures in mR/mAs exposure is to be measured at 120 kVp for mAs values 2 to 10. For abdominal procedures, in air mR/mAs exposure is to be measured at a kVp value between 75 and 85 and for mAs values 20 to 100. For extremity procedures in air mR/mAs exposure is to be measured for a kVp value between 50 and 60 and for mAs values 1 to 10.

(Documentation will indicate the clinical procedures for which the mAs reciprocity condition is being evaluated and the associated technique factors. Measured exposure values and the associated mR/mAs values will also be included.)

4) Timer Accuracy

For x-ray equipment with time settings, the accuracy of the timer shall be evaluated for the time settings greater than 0.05 seconds that are most frequently used.

Example 1: A three phase six pulse generator is used for chest, abdomen and extremity procedures. Chest procedures are performed at 85 to 95 kVp, 300 mA, with exposure times of 0.016 and 0.025 seconds. Extremity procedures are done at 55 to 65 kVp, 100 mA, and at exposure times 0.05 to 0.125 seconds. Abdomens are performed at 75 to 90 kVp, 200 or 300 mA, with exposure times 0.25 to 1.0 seconds. As a minimum, either the timer shall be evaluated for extremity procedures in the range 0.05 to 0.125 seconds or in the range of 0.25 to 1.0 seconds for abdominal procedures.

(Documentation shall identify the x-ray procedures for which the timer is evaluated, time settings being evaluated, and the measured time values.)

5) Exposure Reproducibility

Reproducible exposures are to be evaluated for technique factors used clinically. For a series of exposures, where the technique factors are held constant, the coefficient of variation (COV) for certified x-ray equipment shall be less than or equal to 0.05. (NOTE: The DRC will deem this condition met if the difference between the maximum exposure and the minimum exposure values divided by the average value for four exposures is less than 0.1. Otherwise, additional exposures will be made and the COV calculated.)

Example 1: A facility uses a high frequency generator to perform chest, abdominal and extremity procedures. Chest procedures are performed at 120 kVp and photo timed. The abdominal procedures are performed at 80 kVp using the under table bucky and are also photo timed. The extremity procedures are performed above table with manual kVp and mAs techniques; 50 to 60 kVp and at 0.8 to 5.0 mAs. Reproducibility is to be tested in both the manual and photo timed modes of operation. As a minimum, the unit is to be evaluated for chest and abdominal photo timed procedures and for one set of technique factors that is used manually for extremities. Evaluation of the phototimer is to be performed with a phantom which approximates the attenuation properties of an average adult chest or abdomen.

(Documentation will include the technique factors used in the evaluation, the in-air exposure values obtained, and the calculated COV when necessary. A brief statement of the type of attenuation phantom used is to be included when phototimer reproducibility is evaluated.)

6) X-ray Field Collimation and Alignment

For an x-ray unit designed for use in general purpose radiography, a collimator that produces an x-ray field with step less adjustment of the width and length is required. A light field is present to assist in the alignment of the x-ray field with the image receptor and patient Accurate SID indicators are to be available to assist in positioning the patient and image receptor relative to the x-ray source in a reproducible manner. The following shall be evaluated:

a) X-ray and Light Field Congruence

(Documentation indicates that a test was performed and a conclusion was reached as to whether the sides of the x-ray and light fields agree within 2% of the SID)

b) Light Field Intensity

(Documentation indicates testing was performed and a conclusion reached as to whether the light field intensity is adequate for proper patient positioning and alignment with the image receptor.)

c) X-ray Field Aligns with the Image Receptor

Example 1: A general purpose x-ray unit is only used to perform above table extremity procedures, under table abdominal procedures and chest procedures using a vertical cassette holder with reciprocating bucky.

(Documentation will indicate that the center of the x-ray field aligns with the center of the film within 2% of the SID when using either the vertical cassette holder or under table bucky.)

d) Equipment with a PBL System

If a PBL device is present and used clinically, it is to be evaluated to insure that exposures can not be made unless the field has been collimated to the size of the film/screen system.

Example 1: An x-ray unit is used to do procedures using either the under table bucky or a wall mounted vertical cassette holder. Both the under table bucky and vertical cassette holder are equipped with a PBL system. The PBL system is to be evaluated for both under table and chest procedures. As a minimum, each system should be evaluated with the cassette size most frequently used with the particular system being evaluated; i.e., for chest procedures, the 14 x 17 inch cassette.

(Documentation shall indicate that the evaluation has been performed and the system meets the regulatory standards. Also, the cassette size used to evaluate each system shall be indicated along with the dimensions of the maximum x-ray field size that will allow exposures to be made.)

e) Field Size Indicator

The collimator field size indicator is to be evaluated when under table procedures are performed with x-ray equipment without a PBL system.

(Documentation will indicate that the evaluation has been performed. The collimator field size setting shall be indicated and the size of the measured x-ray field shall be included.)

f) SID Indicators

SID indicators are to be present for positioning of the image receptor relative to the x-ray source.

(Documentation shall indicate that SID indicators are present, that they have been evaluated, and are adequate.)